

REMARKS/ARGUMENTS

Restriction Requirement

A telephonic interview was held between Examiner Darin R. Roberts and Mr. Bryant R. Gold on June 22, 2006. In this interview, an agreement was reached concerning a restriction requirement. Restriction to one of the following inventions Groups was required: Invention I (claims 1-13 & 20-23) and Invention II (claims 14-19). Mr. Gold made a provisional election during the telephonic interview of June 22, 2006 of Invention I, claims 1-13 & 20-23.

Claims 14-19 were withdrawn from further consideration by the Examiner as being drawn to a non-elected invention. Applicants now confirm the election of Invention I claims, without traverse.

The Office Action, mailed July 11, 2006, rejected claims 1-9, 12, 13, 20, 21, and 23. (The office action summary page erroneously lists claim 18 as having been rejected). Claims 10, 11 and 22 were objected to. New Claims 24-27 have been added. Claims 1-13 & 20-27 are pending.

Claims 1 and 2 rejected under 35 U.S.C. §102(e)

Claims 1 and 2 were rejected under 35 U.S.C. §102(e) as being anticipated by Gibson et al (U.S. 20030171758 A1). This rejection is respectfully traversed. In the interest of expediting prosecution, claim 1 has been amended to add a zigzagged conductor wire as an element. Gibson does not disclose a zigzagged conductor wire. Therefore, because an element is missing, claims 1 and 2 are not anticipated by

Gibson. There may be other reasons the claims 1 and 2 are not anticipated. We reserve to argue these other reasons at a later date for this application or in a continuation filing.

Claims 1-5, 8 & 9 rejected under 35 USC §102(b)

Claims 1-5, 8 & 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma (U.S. Pat. No. 6,119,044). This rejection is respectfully traversed. Independent Claim 1, as amended, includes a zigzagged conductor wire. Claims 2-5, 8 and 9 all depend from claim 1 and include a zigzagged conductor wire. Claims 2-5, 8 and 9 are not anticipated by Kuzma '044 because an element, a zigzagged conductor wire, is not disclosed by Kuzma '044.

In addition, in reference to claims 8 & 9, Kuzma '044 does not disclose an "overmold" that caps the stylet channel. Further, Kuzma '044 does not disclose an opening to a stylet channel, which opening is a slit. Figure 14 in Kuzma '044 does not show an overmold that caps the opening to the stylet channel. To the contrary, Figure 14 shows that the opening is conventional—it is merely a hole with no overmold cap. The use of the term "overmolding" in Kuzma '044 [column 7, lines 1-5] is in regards to a method of manufacturing the flexible carrier body 13. Applicants use of "overmold" 75 is as a part (see Applicants' Figure 4, element 75) that caps the entrance of the channel. Thus, "overmold" as a term is used differently than in Kuzma '044. In the present application "overmold" specifies a capping part. By contrast, "overmolding" in Kuzma '044 describes a method for manufacturing the carrier body 13.

There may be other reasons the claims 2-5, 8 and 9 are not anticipated. We reserve the right to argue these reasons at a later date for this application or in a continuation filing.

Claims 6, 7, 12, 13, 20 & 21 rejected under 35 U.S.C. 103(a)

Claims 6, 7, 12, 13, 20 & 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma '044. This rejection is respectively traversed.

Claims 6, 12, and 13 all depend from claim 1, which now includes a zigzagged conductor wire. This element is not disclosed by Kuzma '044. For at least that reason, although there may be other reasons, Claims 6, 12 and 13 are not made obvious by Kuzma '044.

Claim 7 has been canceled. The substance of claim 7 concerning zigzagged conductor wires has been added to claim 1 and all its dependent claims.

In referring to zigzagged conductor wires, as mentioned in original claim 7, the Examiner has stated that, "it was known in the art that zigzag conductor wires can be used to hinder breakage of the conductor wires. Applicants respectfully disagree with the statement that zigzagged conductor wires were known. The known conductors wires in the prior art before this application was filed were either coils (used particularly in pacing leads), straight conductor wires, or straight conductor wires that are stranded together. Zigzagged conductor wires as used in Applicants' cochlear lead device is a novel concept. Since there is an absence of any teaching or suggestion of zigzagged conductor wires in any references mentioned, whether Kuzma '044 or Gibson, a proper

obviousness rejection would have included another reference that discloses zigzagged conductor wires.

The manual of patent examination and procedures (MPEP, 8th Edition) section 2143, Basic Requirements of *Prima Facie* Case of Obviousness states: "To establish a prima case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

Applicants submit that there is no suggestion or motivation in Kuzma '044 to modify what is disclosed to include zigzagged conductor wires. Indeed, Kuzma '044 never mentions zigzagged conductor wires because such a conductor wire had not been conceived by the inventor Kuzma (who incidentally happens to be one of the inventors of this present application). As such, Applicants submit that a *prima facie* case of obviousness has not been established because Kuzma '044 does not disclose any suggestion or motivation to use a zigzagged conductor wire nor has it been established that zigzagged conductor wires were generally known to one of ordinary skill in the art and which zigzagged conductor wires would have been applied to modify the design of Kuzma '044. The third requirement is that the prior art reference, Kuzma '044 must "teach or suggest all the claim limitations." Applicants submit that zigzagged conductor wire is a claim limitation that is not taught or suggested in Kuzma '044.

Therefore, a *prima facie* case of obviousness has not been met and the rejection of
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original claim 7 was improper. Because it is believed that zigzagged conductor wires are novel, and to expedite prosecution of the claims in this application, Applicants have amended claim 1 to include zigzagged conductors. In view of the inclusion of zigzagged conductors to claim 1, Applicants believe that the obviousness rejection under Kuzma '044 of claims 6, 12 and 13, which now depend from amended claim 1, has been overcome.

In addition, claim 6 teaches a super-flexible tip which does not include a stylet insertion channel. As Examiner stated, Kuzma does not disclose such a superflexible tip. The Examiner asserted that, “[i]t would be obvious to one of ordinary skill in the art at the time the invention was made to modify the carrier as taught by Kuzma patent with a super-flexible electrode-baring tip that does not include the stylet insertion channel since it was known in the art that the use of a super-flexible electrode baring carrier tip can be used to minimize the amount of damage done to the cochlea during implantation.” [Office Action, page 7 last paragraph and continuing on page 8].

Applicants respectfully disagree that a super-flexible tip is obvious. Again, a *prima facie* case has not been met. Kuzma '044 does not teach or suggest a superflexible tip. There is no motivation in Kuzma '044 to include a super-flexible tip. For this additional reason, claim 6 is not obvious.

Worley et al. is cited on page 8, second paragraph of the Office Action. Applicants assume that Worley is a typographical error and what was meant was that Kuzma '044 does not teach that the conductor wires are zigzagged.

In reference to the obviousness rejection of claims 20 & 21, the Examiner stated that the “Kuzma patent ['044] does not teach capping the insertion stylet channel

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opening using what can be described as a “pin plug.” [Office Action, page 9, first paragraph]. It was further stated, “It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lead body of the Kuzma device with a pin cap since it was known in the art that capping such an orifice of an implantable device is done to prevent the accumulation of infectious material within the body of the channel. Applicants respectfully disagree that the value of capping the insertion stylet “to prevent the accumulation of infectious material with the body of the channel” was known or appreciated by those skilled in the art prior to the filing of this present application. Indeed, Kuzma ‘044 specifically does not teach capping the insertion stylet channel. The absence of such teaching speaks volumes, in that the value of capping the insertion stylet was not recognized at the time of Kuzma ‘044.

Applying the three prong test for a *prima facie* case of obviousness, (1) there is not any suggestion or motivation to modify the reference, Kuzma ‘044, to cap the insertion stylet, either in Kuzma ‘044 or in the general knowledge of those skilled in the art; (2) there is no reasonable expectation of success because the problem or issue of accumulation of infectious material is not identified by Kuzma ‘044; and (3) Kuzma ‘044 must teach or suggest all the claim limitations, including “capping the insertion stylet opening” as recited in Applicants’ claim 20 -- which Kuzma ‘044 does not. Hence, a *prima facie* case of obviousness is not met, and the obviousness rejection of claims 20 is improper.

In addition, claim 21 provides a specific device configuration for capping the insertion stylet opening with a pin plug having a “head and curved pin.” This element is not disclosed, taught or suggested in Kuzma ‘044 or anywhere else. This method of

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capping with such device is completely new and is specifically designed for the insertion stylet of a small cochlear lead and not some other type of implantable lead. Claim 21 is not obvious, not only because claim 21 depends from claim 20, which claim Applicants submit is also non-obvious, but also because the reason for rejecting claim 21 does not meet a *prima facie* case of non-obviousness.

A *prima facie* case of obviousness is not met for claim 21. First, there is not any suggestion or motivation to modify the reference, Kuzma '044, to fit a pinplug, with a curve tail and head, into the opening of the insertion stylet. Second, there is no reasonable expectation of success, because the problem or issue of accumulation of infectious material is not identified by Kuzma '044. Third, Kuzma '044 must teach or suggest all the claim limitations, including "inserting the head of a pin plug in the lead to seal the channel opening" as recited in Applicants' claim 21, which Kuzma '044 does not. Thus, the obviousness rejection of claim 21 is improper.

Allowable subject matter in claims 10, 11 & 22

The Examiner indicated that claims 10, 11 & 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Applicants express appreciation for this statement of allowability. Claims 10 and 11 have been re-written into independent claims. Claim 22 has not been amended because it is believed that claim 20 is in condition for allowance and therefore the objection to it as being dependent upon a rejected base claim is moot.

Claim 23

Claim 23 apparently was rejected (as listed in Office Action Summary page). However, it was not included in any of the specific rejections. Applicants believe that claim 23 is in condition for allowance at least for the reason that it recites a pin plug having a head and tail pin. In addition, claim 23 recites an insertion tool which is not disclosed or suggested in either Gibson or Kuzma '044.

New Claims 24-27 Added

New claims 24-27 have been added. Independent claim 24 includes the part, "wherein the most distal tip of the lead that includes a subset of the electrode array is constructed as a super-flexible tip; and wherein the super-flexible tip does not include the stylet insertion channel and which super-flexible tip has a substantially smaller thickness than the remainder of the distal lead containing the electrode array that is not super-flexible." Applicants submit that a super-flexible tip is not taught or suggested by either Gibson or Kuzma '044. As such, neither references cited anticipate or make obvious new claims 24-27.

Petition for one-month extension of time

Applicants request a one-month extension of time. With a one-month extension of time, this response is due November 13, 2006.

Conclusion

New independent claim 24 and new dependent claims 25-27 have been added. Two independent claims have been amended to become independent claims. Claim 7
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has been canceled. Claims 14-19 were withdrawn as being drawn to a non-elected invention. As such, claims 1-6, 8-13, 20-27 are pending.

In addition, a one-month extension of time has been requested. A fee transmittal statement is included with this Amendment A. Please charge any required fees or credit any overpayment to **Deposit Account Number 50-0648.**

An early indication of allowability of all pending claims is courteously requested. The Examiner is encouraged to telephone the undersigned to resolve any issues concerning this application.

Respectfully Submitted,

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Date

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